Amendments to the Claims

The listing of claims will replace all prior versions, and listings of claims in the application.

Claim 1 (currently amended): A method of treating cancer or metastasis thereof in a mammal, comprising:

administering into a muscle of a mammal in need of cancer treatment, a DNA plasmid comprising a polynucleotide which encodes interferon-alpha or an active fragment thereof, operably associated with a promoter;

wherein said DNA plasmid is administered free from *ex vivo* cells;

wherein said interferon alpha is expressed *in vivo*, and is present in the blood stream of said mammal in an amount effective to treat said cancer, or metastasis thereof.

Claim 2 (cancelled)

Claim 3 (previously presented): The method of claim 1, wherein said plasmid further comprises a polyadenylation signal and transcription termination signal operably associated with said polynucleotide.

Claim 4 (previously presented): The method of claim 1, wherein said cancer is selected from the group consisting of renal cell carcinoma, colorectal carcinoma, lymphoma, Kaposi's sarcoma, melanoma, prostate cancer, ovarian cancer, lung cancer, liver cancer, head and neck cancer, bladder cancer, uterine cancer, bone cancer, leukemia, breast cancer, non-melanoma skin cancer, glioma, solid cutaneous tumor, epidermoid carcinoma, metastases of any of thereof, and combinations of any of thereof.

Claim 5 (original): The method of claim 4, wherein said cancer is a lung metastasis of any of said cancers.

Claim 6 (original): The method of claim 4, wherein said cancer is a liver metastasis of any of said cancers.

Claim 7 (previously presented): The method of claim 1, wherein said muscle tissue is skeletal muscle.

Claims 8-15 (cancelled)

Claim 16 (previously presented): The method of claim 1, wherein said interferon alpha is a polypeptide comprising amino acids 1 to 166 of SEQ ID NO:10.

Claim 17 (previously presented): The method of claim 16, wherein said interferon alpha is a polypeptide comprising amino acids -23 to 166 of SEQ ID NO:10.

Claim 18 (previously presented): The method of claim 1, wherein said DNA plasmid is VR4112 (SEQ ID NO:2).

Claims 19-29 (cancelled)

Claim 30 (previously presented): The method of claim 1, wherein said cancer is melanoma or metastasis thereof.

Claim 31 (original): The method of claim 30, wherein said cancer is metastasis of melanoma.

Claim 32 (original): The method of claim 31, wherein the metastasis of melanoma is lung metastasis.

Claim 33 (previously presented): The method of claim 1, wherein said cancer is glioma.

Claim 34 (previously presented): The method of claim 1, wherein said cancer is epidermoid carcinoma.

Claim 35 (previously presented): The method of claim 1, wherein said DNA plasmid is dissolved in an aqueous solution.

Claims 36-37 (cancelled)

Claim 38 (previously presented): The method of claim 1, wherein said DNA plasmid is administered free from association with transfection-facilitating proteins, viral particles, liposomes, cationic lipids, and calcium phosphate precipitating agents.

Claim 39 (previously presented): The method of claim 1, wherein said DNA plasmid is administered as a complex of said DNA plasmid and one or more cationic compounds selected from the group consisting of cationic lipids, cationic peptides, cationic proteins, cationic polymers other than lipids or peptides, and mixtures thereof.

Claim 40 (original): The method of claim 39, wherein said one or more cationic compounds are one or more cationic lipids.

Claim 41 (previously presented): The method of claim 40, wherein said compounds further comprise one or more neutral lipids.

Claim 42 (cancelled)

Claim 43 (previously presented): The method of claim 1, wherein said DNA plasmid further comprises a region regulating expression operably associated with said polynucleotide.

Claims 44-45 (cancelled)

Claim 46 (previously presented): A method of treating cancer, or metastasis thereof, in a mammal, comprising:

the method of claim 1 in combination with one or more additional cancer treatment methods selected from the group consisting of surgery, radiation therapy, chemotherapy, immunotherapy, and gene therapy.

Claim 47 (previously presented): The method of claim 46, wherein said DNA plasmid is administered prior to the commencement of said one or more additional cancer treatment methods.

Claim 48 (previously presented): The method of claim 46, wherein said DNA plasmid is administered during the practice of said one or more additional cancer treatment methods.

Claim 49 (previously presented): The method of claim 46, wherein said DNA plasmid is administered after the end of said one or more additional cancer treatment methods.

Claim 50 (previously presented): The method of claim 1, wherein said mammal is human.

Claims 51-65 (cancelled)

Claim 66 (currently amended): A method of treating cancer in a mammal, comprising:

administering into the peritoneal cavity of said mammal in need of cancer treatment, a DNA plasmid comprising a polynucleotide which encodes interferon alpha or an active fragment thereof, operably associated with a promoter, wherein said DNA plasmid is administered free from *ex vivo* cells or *ex vivo* cellular material; and wherein said interferon alpha is delivered to a tumor, or metastases thereof, in a therapeutically effective amount.

Claims 67-68 (cancelled)

Claim 69 (previously presented): The method of 66, wherein said tumor disseminates in said peritoneal cavity.

Claim 70 (cancelled)

Claim 71 (previously presented): The method of claim 66, wherein said DNA plasmid is free from association with transfection-facilitating proteins, viral particles, and calcium phosphate precipitating agents.

Claim 72 (previously presented): The method of claim 66, wherein said DNA plasmid is administered as a complex with one or more cationic lipids.

Claim 73 (previously presented): The method of claim 72, wherein said complex further comprises one or more neutral lipids.

Claim 74 (previously presented): The method of claim 73, wherein said DNA plasmid is complexed with (±)-N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-1-propaniminium bromide and 1,2-dioleoyl-glycero-3-phosphoethanolamine.

Claims 75-76 (cancelled)

Claim 77 (original): The method of claim 66, wherein said mammal is a human.

Claim 78 (currently amended): A method of transfecting malignant cells in a mammal, comprising:

administering into the peritoneal cavity of said mammal <u>in need of cancer treatment,</u> a DNA plasmid comprising a polynucleotide encoding interferon alpha, or an active fragment thereof, operably associated with a promoter, wherein said DNA plasmid is administered free from *ex vivo* cells or *ex vivo* cellular material; and wherein said plasmid is delivered to and expressed in malignant cells within said peritoneal cavity.

Claims 79-82 (cancelled)

Claim 83 (previously presented): The method of claim 78, wherein said DNA plasmid is free from association with transfection-facilitating proteins, viral particles, and calcium phosphate precipitating agents.

Claim 84 (previously presented): The method of claim 78, wherein said DNA plasmid is administered as a complex with one or more cationic lipids.

Claim 85 (previously presented): The method of claim 78, wherein said complex further comprises one or more neutral lipids.

Claim 86 (previously presented): The method of claim 85, wherein said DNA plasmid is complexed with (±)-N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-1-propaniminium bromide and 1,2-dioleoyl-glycero-3-phosphoethanolamine.

Claims 87-103 (cancelled)